COMMISSION IMPLEMENTING REGULATION (EU) 2023/341

of 15 February 2023

concerning the renewal of the authorisation of vitamin E as a feed additive for all animal species and repealing Regulation (EU) No 26/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) Vitamin E was authorised for 10 years as a feed additive for all animal species by Commission Regulation (EU) No 26/2011 ([2]).

(3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, five applications were submitted for the renewal of the authorisation of vitamin E in the form of all-rac-alpha-tocopheryl acetate and one for the renewal of the authorisation of vitamin E in the form of RRR-alpha-tocopheryl acetate as feed additives for all animal species, requesting the additives to be classified in the additive category 'nutritional additives' and the functional group 'vitamins, pro-vitamins and chemical well-defined substances having similar effect'. Those applications were accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 17 March 2021 ([3]) and 10 November 2021 ([4]) that the applicants have provided evidence that vitamin E remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised and that no concern for user safety is expected from the use of the active substance. The Authority could not conclude, due to the lack of information, on its skin sensitisation potential.

(5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([5]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessments are applicable for the current applications.

(6) The assessment of vitamin E shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Regulation (EU) No 26/2011 of 14 January 2011 concerning the authorisation of vitamin E as a feed additive for all animal species (OJ L 11, 15.1.2011, p. 18).
([3]) *EFSA Journal* 2021;19(4):6529, 6530, 6531, 6532 and 6533.
([4]) *EFSA Journal* 2021;19(12):6974.
([5]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

(7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives. Those protective measures should comply with Union legislation on worker safety requirements.

(8) As a consequence of the renewal of the authorisation of vitamin E in the form of all-rac-alpha-tocopheryl acetate and of vitamin E in the form of RRR-alpha-tocopheryl acetate as feed additives, as well as the expiry of the authorisation of vitamin E in the form of RRR-alpha-tocopherol, Regulation (EU) No 26/2011 should be repealed.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of vitamin E, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the renewal of the authorisation.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the substance and preparations specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemical well-defined substances having similar effect', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EU) No 26/2011 is repealed.

Article 3

1. The substance and preparations specified in the Annex and premixtures containing them, which are produced and labelled before 8 September 2023 in accordance with the rules applicable before 8 March 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substance and preparations specified in the Annex which are produced and labelled before 8 March 2024 in accordance with the rules applicable before 8 March 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substance and preparations specified in the Annex which are produced and labelled before 8 March 2025 in accordance with the rules applicable before 8 March 2023 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a700	'Vitamin E' or 'all-rac-alpha-tocopheryl acetate'	*Additive composition* All-rac-alpha-tocopheryl acetate Liquid form *Characterisation of active substance* All-rac-alpha-tocopheryl acetate $C_{31}H_{52}O_3$ CAS number: 7695-91-2 Purity: > 93 % Produced by chemical synthesis *Analytical method* (1) 1. For the determination of vitamin E (oil form) in feed additives: European Pharmacopoeia Ph. Eur. 07/2011:0439. 2. For the determination of vitamin E (powder form) in feed additives: European Pharmacopoeia Ph. Eur. 01/2011:0691. 3. For the determination of the level of authorised vitamin E in compound feed: Commission Regulation (EC) No 152/2009 (2).	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used also via water for drinking. 3. If vitamin E content is mentioned in the labelling, the following equivalencies for the units of measurement of the contents shall be used: — 1 mg all-rac-alpha-tocopheryl acetate = 1 IU 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin protection.	8 March 2033

3a700i	'Vitamin E' or 'all-rac-alpha-tocopheryl acetate'	*Additive composition* Preparation containing ≥ 50 % all-rac-alpha-tocopheryl acetate Solid form *Characterisation of active substance* All-rac-alpha-tocopheryl acetate $C_{31}H_{52}O_3$ CAS number: 7695-91-2 Purity: > 93 % Produced by chemical synthesis *Analytical method* (1) 1. For the determination of vitamin E (oil form) in feed additives: European Pharmacopoeia Ph. Eur. 07/2011:0439. 2. For the determination of vitamin E (powder form) in feed additives: European Pharmacopoeia Ph. Eur. 01/2011:0691. 3. For the determination of the level of authorised vitamin E in compound feed: Regulation (EC) No 152/2009 (2).	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used also via water for drinking. 3. If vitamin E content is mentioned in the labelling, the following equivalencies for the units of measurement of the contents shall be used: — 1 mg all-rac-alpha-tocopheryl acetate = 1 IU 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin protection.	8 March 2033

3a700ii	'Vitamin E' or 'RRR-alpha-tocopheryl acetate'	*Additive composition* Preparation containing ≥ 25 % RRR-alpha-tocopheryl acetate Solid form *Characterisation of active substance* RRR-alpha-tocopheryl acetate $C_{31}H_{52}O_3$ CAS number: 58-95-7 Purity: > 40 % Chemically synthesised from vegetable oils. *Analytical method* (1) 1. For the determination of vitamin E (oil form) in feed additives: European Pharmacopoeia EP-1257. 2. For the determination of vitamin E (powder form) in feed additives: European Pharmacopoeia Ph. Eur. 01/2011:0691. 3. For the determination of the level of authorised vitamin E in compound feed: Regulation (EC) No 152/2009 (2).	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive may be used also via water for drinking. 3. If vitamin E content is mentioned in the labelling, the following equivalencies for the units of measurement of the contents shall be used: — 1 mg RRR-alpha-tocopheryl acetate = 1,36 IU 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin protection.	8 March 2033

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports.
(2) Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).